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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/313,628	05/18/1999	GARY D. HODGEN	P/1890-201(D	4153

7590 08/26/2003

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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	PAPER NUMBER
1617	20

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/313,628	Hodgen
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 30, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The response and request for continuing prosecution filed June 30, 2003 have been received and entered into the file.

Applicant's arguments filed June 30, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 21-33 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines that would be a "Selective Estrogen Receptor Modulator" or an "agent which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "Selective Estrogen Receptor Modulator(s)" or "agent(s) which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "Selective Estrogen Receptor Modulator" compounds, or "agent(s) which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator",

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 21-33 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 21-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-33 are rendered indefinite by the phrases "Selective Estrogen Receptor Modulator" or an "agent which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are "Selective Estrogen Receptor Modulator(s)", or "agent(s) which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 21-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-33 are rendered indefinite by the phrase "modulate" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining those effects desired when the skilled artisan is required to "modulate" the bleeding side effects are not set forth in the instant specification. Examiner notes the term "modulate" includes increasing, decreasing, maintaining the same level, or altering the frequency, to a lesser, or greater extent. Those explanations setting forth what actions are included in action falling under "modulate" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Jones et al, Basu, and Schane et al, in view of Merck Manual.

Jones et al, Basu, and Schane et al teach the claimed, benzothiophenes, clomiphene and danazoles, respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form, as antifertility medicaments. This medicament is taught as useful for independently providing contraception, viewed by the skilled artisan as differing form the claimed use, not at all. Claims 21-33, and the primary references, differ as to:

1) the concomitant employment of these medicaments

2) administration levels of the medicaments, and

3) recitation of bleeding amelioration.

It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-fertility agents. It would follow that the recited claims define

prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 28 and 29 specifically require a discrete medicament dose. Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed contraception methods concomitantly employing therapeutics old and well known for the same contraceptive use.

Claims 21-33 require the amelioration of bleeding in the practice of the invention as envisioned. Attention is directed to the Merck Manual of Medical Information teaching initial bleeding as a normal side effect collateral to administration of oral contraceptives. The Merck Manual of Medical Information teaches bleeding as normal, and not a chronic side effect to oral contraceptive use. Thus, the skilled artisan would see conventional oral contraceptive administration as inherently providing "modulation" for the bleeding encountered collateral to oral contraceptive administration. If the claims are directed to chronic bleeding collateral to oral contraceptive administration, this specific use must be claimed, and illustrated. Absent such limitations, the instant

claimed use, and that set forth in the Examiner cited prior art are not patentably distinct.

RESPONSE TO ARGUMENTS

Examiner again notes those arguments supporting amendment limiting the claims to "human" subjects. Additionally, Examiner notes the instant obviousness rejection is not avoided by this amendment. Jones et al teach the claimed compounds "as contraceptive in living beings" (column 9, lines 31-32), which Examiner would view as meaning human. A most reasonable dictionary definition of "being" is an individual, or human. Thus, the skilled artisan would see the Jones et al compounds as useful for treating humans, not only animals, as averred by Applicants.

Applicants constructively aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither convincing, nor reasonably commensurate in scope with the instant claims. Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect

conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

The claimed invention recites providing contraception in **premenopausal human"** females: which group reads on any female who is not menopausal. Those individuals claimed do not appear to be the group envisioned by Applicants, yet are those individuals disclosed in the Examiner cited prior art. As set forth in paper 17, rebuttal arguments regarding pre-menopausal females have been considered, but are found unconvincing. Examiner believes the proper tern for those individuals entering menopause would be peimenopause, or being in the climacteric phase. Prior to menopause, menses and ovulation become erratic; yet those individuals experiencing peimenopause possess the same reproductive strategies as those individuals not experiencing peimenopause. Simply stated, the instant claims read on all female individuals not menopausal; most of the female population

Those claims presented read on employing various medicaments to achieve a desired therapeutic goal. As presented, the nature, or number of these agents are not distinctly set forth by the presented claims. Additionally, the therapeutic goal herein recited is unclear. Applicant employs the term "modulate" to limit the effect desired, rendering the claims indefinite, and placing a burden of undue experimentation on the skilled artisan. Modulate's simple meaning is to adjust or adapt to a certain proportion, not distinguishing the direction, or degree of the adjustment, or adaption. The skilled artisan would not know if the intent was to moderate the side effects, or intensify the side effects. Additionally, the skilled artisan would not know if these side effects could be beneficial, or unwanted. Simply stated, the claims fail to delineate the invention constructively averred by Applicant. .

Applicant's rebuttal arguments regarding selective estrogen receptor modulators (SERM) have been considered, but are unconvincing. The instant rejection is for undue experimentation, not a failure to conceptually grasp the SERM nature.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of

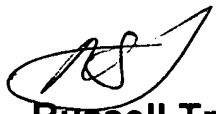
novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate".. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Rebuttal arguments regarding pre-menopausal females have been considered, but are found unconvincing. Examiner believes the proper tern for those individuals entering menopause would be peimenopause, or being in the climacteric phase. Prior to menopause, menses and ovulation become erratic; yet those individuals experiencing peimenopause possess the same reproductive strategies as those individuals not experiencing peimenopause. Those of normal skill in the art would be motivated to employ contraceptive regimens indistinguishable from those required by

the normal female population, absent information to the contrary. Efforts to contraindicate the instant obviation with undated textual material are not successful. A contraindication must have been in placé at the time of the instant invention. Thus, undated material, by its nature is unconvincing. Attention is directed to Yen et al (supplied by Applicant without a date) at page 1041, paragraph 3, stating the only positive statement regarding clomiphene: "The work of Docke (564) with bilateral implants of clomiphene in the brain indicates the drug blocks ovulation induction by estrogen". The Yen et al teaching, regarding clomiphene, differs from the Examiner cited prior art, and the method herein claimed, not at all.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



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Art Unit 1617